

have had a real-life devastating impact on the economy of Washington State.

Today I join with many of my colleagues in demanding that these employees, upon evidence of their guilt is established, be immediately terminated. It is unacceptable that these employees have simply been counseled for their planting of evidence. Federal employees should be held accountable for their actions—period.

Further, I support a complete review of the lynx study as well as a review of any other projects on which these employees may have worked. The integrity of these agencies and our future efforts to protect threatened and endangered species depends on these reviews. As a member of the Interior Appropriations Subcommittee, I intend to make sure that this kind of activity never happens again and that the agencies involved are not perpetrating a fraud on the American people. That is my highest responsibility.

BEST PHARMACEUTICALS FOR CHILDREN ACT

SPEECH OF

HON. BART STUPAK

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Tuesday, December 18, 2001

Mr. STUPAK. Mr. Speaker, I rise tonight to urge Members to vote against the pediatric exclusivity bill, S. 1789. It is the product of a flawed negotiating process, a flawed legislative process, and a flawed regulatory process which was instituted back in 1997.

First approved in 1997, pediatric exclusivity granted drug companies an extra six-month extension on their patent if they would conduct a study to determine what the effects were on young people. The FDA sends a written request for a pediatric study to the drug company. Upon completion of the study, FDA grants a six month extension of the patent monopoly—the “pediatric exclusivity”—which the drug companies then use as a marketing tool to promote and increase the drug's sales.

What I find horrifying is the grant of exclusivity takes place after the drug company does its study but before anyone knows what is included in the results of the study. Nothing is said to the general public—which includes parents and pediatricians—or prescribing physicians about the safety, effectiveness, or dosage requirements. Under S. 1789, there is no requirement to change the labeling on the drug to reflect the changes that may be needed when the drug is dispensed to young people. There is no label to tell doctors, patients, and their families the proper dosage, or how to dispense or use the drug.

My argument has always been this: before you grant pediatric exclusivity to a pharmaceutical company and before this exclusivity is then marketed as being FDA approved for pediatric use, shouldn't you at least know what is the effect of the drug on young people?

Under current law—and this bill would extend current law after the study is completed, exclusivity is granted, but whether the drug helps or hurts young people remains a secret and is not disclosed to the doctors, patients,

and their families for an average of 9 months. Shouldn't this information get out to these people before they ingest this medicine?

I have a chart, which I have used on the floor before. It highlights the problems with S. 1789, which does not require labeling changes until 11 months after the drug is being used in the pediatric population. How many of you would give your child a drug and not know whether it helps or harms your child until 11 months later?

There have been 33 drugs granted pediatric exclusivity. Only 20 have been re-labeled to reflect the results of the pediatric study, and even those label changes have taken an average of 9 months.

For 9 months, doctors, patients, and their families have no idea if the child is receiving the proper dosage or even if the drug is really safe!

Now why can't doctors, patients, and their families know this information before the grant of pediatric exclusivity is given? I was not allowed a chance to offer my amendment before the full House. My amendment is very simple and very commonsense: before pediatric exclusivity is granted, all drugs must be labeled especially for pediatric use.

Under other prescription drug patent extension programs, labeling is an absolute prerequisite to receiving patent extension. But not pediatric exclusivity. Why would we treat our children any differently?

For the love of me, I cannot understand why the majority does not want doctors, patients, and their families to know the effect of drugs may have on children!

What is the proper dosage? What is the efficacy? What is the safety level for our children?

Why do we wait an average of 9 months before we see proper labeling? Why must we wait to find out if a child has received the proper dosage?

Let us defeat this legislation. I urge a no vote.

UNITED STATES SECURITY ACT

HON. JERRY F. COSTELLO

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

Thursday, December 20, 2001

Mr. COSTELLO. Mr. Speaker, I rise today in support of the Democratic Caucus' Homeland Security bill, the United States Security Act (USA Act).

This legislation is a collaborative effort crafted by my democratic colleagues on the Homeland Security Task Force. I was honored to have served as the vice chair of the Transportation Security task force with my friend, BOB BORSKI, who chaired the task force.

The USA Act addresses funding needs to improve our homeland security in the following areas: public health, transportation, physical and informational infrastructure, law enforcement and the military. As the attacks of the 11th clearly and unfortunately demonstrated, our nation is vulnerable to attack. This bill goes a long way to minimize those vulnerabilities.

In the past five years—and prior to the 11th—there have been international events

which highlighted potential weaknesses in our transportation systems. In Tokyo, Japan, individuals caused harm by releasing sarin gas in the subway system. The USGS *Cole* was attacked in a seaport that, although in Yemen, was considered safe. While these attacks occurred overseas, they could have taken place here in the States.

With the passage of the Aviation Security Act earlier this year, significant improvements to aviation security were mandated. However, other modes of transportation could still be susceptible to attack. This legislation authorizes funds to secure bridges, tunnels, dams, seaports, rail, and public transit.

Specifically, the bill provides \$3.6 billion to strengthen bridge and tunnel structures, improve inspection facilities and the inspection of Hazmat materials on highways, supply the traveling public with real-time information about availability roads and bridges if terrorist attacks were to occur again, and improve security for locks and dams. It also provides \$992 million to enhance security at our seaports by increasing coast guard personnel, establishing a sea marshal program, requiring transponders for foreign vessels in U.S. waters, and screening ship cargo by x-ray. To improve security on transit systems, \$3.2 billion is authorized. Funds would be used to hire additional security personnel, improve communications and refine mass transit evacuation plans. With the appropriation of funds, the security of these transportation systems will markedly improve.

The USA Act also authorizes funds to strengthen communities responses to emergency incidents. This is done by increasing the number of firefighters, providing grants to communities and first responders and improving technology so that important information can be more readily shared between local, state and federal governments. Our nation's first responders are an integral component in response to a terrorist attack, and we must ensure that they are well prepared.

In addition, the bill also takes major steps towards improving the preparedness of the military to effectively fight terrorism and preventing the proliferation of weapons of mass destruction. We have the best military in the world; however, the war on terrorism is unlike any we've ever fought, and enhancement of current training is important.

Mr. Speaker, I believe that we have produced a good bill. This legislation addresses many real needs in enhancing the security of the United States. I urge my colleagues to join me in support of the legislation.

HONORING THE DEDICATED SERVICE OF DANIEL HARTER

HON. BART GORDON

OF TENNESSEE

IN THE HOUSE OF REPRESENTATIVES

Thursday, December 20, 2001

Mr. GORDON. Mr. Speaker, I rise today to bid farewell to Daniel Harter, an intern with my office. Daniel has provided a unique perspective along with legal expertise as a member of my staff for the past three months, and became an invaluable resource.